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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/623,611	10/06/2000	Maria Galanis	674537-2002	3929
20999	7590	07/13/2006	EXAMINER	
FROMMER LAWRENCE & HAUG 745 FIFTH AVENUE- 10TH FL. NEW YORK, NY 10151			OUSPENSKI, ILIA I	
			ART UNIT	PAPER NUMBER
			1644	
DATE MAILED: 07/13/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/623,611	<b>Applicant(s)</b> GALANIS ET AL.	
	<b>Examiner</b> ILIA OUSPENSKI	<b>Art Unit</b> 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 26 April 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 2, 4 - 9, 12 - 21, 28, 34 - 35, 38, and 42 - 43 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 2, 4 - 9, 12 - 16, 18 - 21, 28, 34 - 35, 38, and 42 - 43 is/are allowed.
- 6) ☒ Claim(s) 17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                                                        |                                                                                         |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____                                                |

## DETAILED ACTION

1. Applicant's amendment/remarks, filed 04/26/2006, are acknowledged.

Claims 1, 3, 10 – 11, 22 – 27, 29 – 33, 36 – 37, and 39 – 41 have been cancelled previously.

Claims 2, 21, and 28 have been amended.

Claims 42 and 43 have been added.

**Claims 2, 4 – 9, 12 – 21, 28, 34 – 35, 38, and 42 – 43 are pending.**

2. This Office Action will be in response to applicant's amendment and arguments, filed 04/26/2006.

The rejections of record can be found in the previous Office Action, mailed 04/21/2006.

The text of those sections of Title 35 USC not included in this Action can be found in a prior Office Action.

***3. The objections and rejections of record have been withdrawn in view of Applicant's amendment and arguments, except as set forth herein.***

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4. Claim 17 stands rejected under **35 U.S.C. 112, first paragraph**, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention.

The rejection of record is reiterated herein:

It is apparent that antibodies cAB-Lys3 and V86 are required to practice the claimed invention. As required elements, they must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. If they are not so obtainable or available, the enablement requirements of 35 USC 112, first paragraph, may be satisfied by a deposit of the pertinent cell lines / hybridomas which produce these antibodies. See 37 CFR 1.801-1.809. In addition to the conditions under the Budapest Treaty, applicant is required to satisfy that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent in U.S. patent applications. Amendment of the specification to recite the date of deposit and the complete name and address of the depository is required. As an additional means for completing the record, applicant may submit a copy of the contract with the depository for deposit and maintenance of each deposit.

It is noted that biological materials must be both known and readily available to the public (See MPEP 2404.01). Neither concept alone is sufficient. If Applicant or other members of the public were able to obtain the materials in question from a given depository or other source prior to and after the filing date of the application does not establish that upon issuance of a patent on the instant application such material would continue to be accessible to the public. Applicant did not make of record any of the facts and circumstances surrounding the access to the biological materials from the depository or other source, nor is there any evidence as to the depository's policy regarding the material if a patent would be granted. Further, there is no assurance that the depository would allow unlimited access to the material if the application has matured into a patent. In the absence of evidence that the cAB-Lys3 and V86 antibodies are readily available to the public and that all restrictions imposed by the depositor on

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the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent, the specification does not provide a sufficient enabling description of the claimed invention.

Applicant's arguments have been fully considered but have not been found convincing.

Applicant argues that antibodies cAB-Lys3 and V86 are known and readily available, because searches of public and commercial databases reveal references that contain the names of these antibodies.

This is not found persuasive, because, as none of these references have been made of record in the instant application, it has not been possible to ascertain whether the references provide evidence of public knowledge or availability.

Applicant further argues that the recited antibodies can be made without undue experimentation, because its isolation is taught in detail in WO and US application publications.

This is not found persuasive, because, as a person of skill in the art is aware, it is possible and predictable to obtain an antibody specific for the same antigen as taught in the art, and often possible to obtain an antibody with similar functional characteristics to the one taught in the art; however, such antibody that a skilled artisan can obtain will not be the "cAB-Lys3" antibody specifically recited in the instant claims.

Applicant further argues that the V86 antibody complies with the requirements of MPEP Section 2404, because it is claimed in US Patent 6,140,470, and thus is presumed to be satisfy the deposit requirements.

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The Examiner has made a diligent effort to obtain the record of the Patent (USSN 08/983,607); however, the application file was not available to the Examiner at this time. Thus, the Examiner has been unable to verify whether the deposit of the V86 antibody has been made in compliance with the requirements of 37 CFR 1.801-1.809 in application USSN 08/983,607, now US Patent 6,140,470.

Therefore, the rejection of record is maintained for the reasons of record.

***5. Conclusion: claim 17 stands rejected.***

***Claims 2, 4 – 9, 12 – 16, 18 – 21, 28, 34 – 35, 38, and 42 – 43 appear to be allowable.***

6. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ILIA OUSPENSKI whose telephone number is 571-272-2920. The examiner can normally be reached on Monday-Friday 9 - 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ILIA OUSPENSKI, Ph.D.

Patent Examiner

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July 7, 2006

  
PHILLIP GAMBEL, PH.D.   
PRIMARY EXAMINER  
